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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/534,082	12/12/2005	Shuji Hinuma	68137(46342)	9415
21874 7590 09/04/2008 EDWARDS ANGELL PALMER & DODGE LLP P.O. BOX 55874 BOSTON, MA 02205				
EXAMINER				
SWARTZ, RODNEY P				
ART UNIT		PAPER NUMBER		
1645				
MAIL DATE		DELIVERY MODE		
09/04/2008		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/534,082

Applicant(s)

HINUMA ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28, 58, 60 and 62-73 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 3-5, 8 and 9 is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 7, 10-28, 58, 60 and 62-73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. Applicants' Response to Office Action, received 12 May 2008, is acknowledged. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 12, 13, 14, 19, 22, 23, 24, 25, 26, 27, 28, 58, and 60 have been amended. Claim 59 has been canceled. New claims 62-73 have been added.
2. Claims 1-28, 58, 60, and 62-73 are pending and under consideration.

Objection/Rejection Withdrawn or Moot

3. The objection to Figure 4 is withdrawn.
4. The objection to the specification, Page 15, line 29, is withdrawn in light of the amendment of the specification.
5. The rejection of claims 3 and 4 under 35 U.S.C. 112, second paragraph, as being indefinite for "formylated" is withdrawn in light of the amendment of the claims.
6. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in light of the amendment of the claim.
7. The rejection of claims 8 and 9 under 35 U.S.C. 112, second paragraph, as being indefinite for "formylated" is withdrawn in light of the amendment of the claims.
8. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being indefinite for "according to claim 1" is withdrawn in light of the amendment of the claim.
9. The rejection of claim 4 under 35 U.S.C. 112, second paragraph, as being indefinite for "according to claim 1" is withdrawn in light of the amendment of the claim.
10. The rejection of claim 5 under 35 U.S.C. 112, second paragraph, as being indefinite for "according to claim 1" is withdrawn in light of the amendment of the claim.
11. The rejection of claim 8 under 35 U.S.C. 112, second paragraph, as being indefinite for "according to claim 6" is withdrawn in light of the amendment of the claim.

12. The rejection of claim 9 under 35 U.S.C. 112, second paragraph, as being indefinite for "according to claim 6" is withdrawn in light of the amendment of the claim.
13. The rejection of claim 24 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in light of the amendment of the claim.
14. The rejection of claim 25 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in light of the amendment of the claim.
15. The rejection of claim 26 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in light of the amendment of the claim.
16. The rejection of claim 27 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in light of the amendment of the claim.
17. The rejection of claim 28 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn in light of the amendment of the claim.
18. The rejection of claim 59 under 35 U.S.C. 101 for "use" claim, is moot in light of the cancelation of the claim.
19. The rejection of claim 59 under 35 U.S.C. 112, second paragraph, as being indefinite for lacking steps, is moot in light of the cancelation of the claim.
20. The rejection of claim 59 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is moot in light of the cancelation of the claim.
21. The rejection of claim 58 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is withdrawn.
22. The rejection of claim 60 under 35 U.S.C. 112, second paragraph, as being indefinite for dependence from rejected claims, is withdrawn.

Rejections Maintained

23. The rejection of claims 1, 2, 6, 7, and 10-14 under 35 U.S.C. 112, second paragraph, as being indefinite for "optionally formylated" is maintained for reasons of record.

Applicants argue that the amendment of the claims to insert "if any" obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive for the reasoning put forth in the original rejection. It is unclear what limitation is placed upon the claims by "optionally" formylating a methionine which is present at the terminus of the sequence.

24. The rejection of claims 15-23 under 35 U.S.C. 112, second paragraph, as being indefinite is maintained for reasons of record.

Applicants argue that the genus of peptides to which the antibodies (are drawn) is clearly and definitely described, especially in view of the amendments to claims 6 and 1.

The examiner has considered applicants' argument, but does not find it persuasive because of the unknown amino acid sequences in a sequence having $\geq 90\%$ homology to sequences actually listed.

25. The rejection of claim 58 under 35 U.S.C. 112, first paragraph, scope of enablement, is maintained for reasons of record.

Applicants argue that the amendment of the claim, now reciting those diseases in which a relationship between the receptor FRPL1 and the disease has been published. Applicants submitted references to support the relationship between the receptor FRPL1 and the diseases listed. In addition, applicants argue that it would not require undue experimentation by one of skill in the art to practice the claimed invention, i.e., a method of preventing or treating the various listed diseases.

The examiner has considered applicants' arguments and considered the submitted references, but does not find them persuasive. While there may be a "relationship" between the listed diseases and the claimed peptides, the specification nor the art support the claim that compositions of the claimed peptide will actually prevent or treat the listed diseases.

New Rejections/Objections Necessitated by Amendment

Claim Objections

26. Claim 14 is objected to because of the following informalities: line 1, there should be a comma between the number 10 and 11. Appropriate correction is required.

Claim Rejections - 35 USC § 112

27. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

28. Newly amended Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, the claim is drawn to a kit comprising (A), (B). It is unclear if the kit comprises "A and B", or "A or B".

29. Newly amended Claim 28 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, the claim is drawn to a kit comprising (A), (B). It is unclear if the kit comprises "A and B", or "A or B".

30. Newly amended Claim 58 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, the claim is drawn to a method comprising administering (i), (ii), (iii). It is unclear if the method comprises "i and ii and ii", "I or ii or iii", or some other combination.

31. Newly amended Claim 60 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, the claim is drawn to a method comprising administering (i), (ii), (iii). It is unclear if the method comprises "i and ii and ii", "I or ii or iii", or some other combination.

32. Newly added claims 62, 65-69, and 73 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a peptide sequence wherein "a methionine residue at the N-terminus is optionally formylated". It is unclear what limitation this places on the claimed peptide. Claims 65-69 and 73 depend from claim 62, but do not clarify the issue.

33. Newly added claim 70 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method of utilizing a peptide "according to claim 2". Claim 2 is a peptide sequence wherein "a methionine residue at the N-terminus is optionally formylated". It is unclear what limitation this places on the claimed peptide.

34. Newly added claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method of utilizing a peptide "according to claim 1". Claim 1 is a peptide sequence wherein "a methionine residue at the N-terminus is optionally formylated". It is unclear what limitation this places on the claimed peptide.

35. Newly added claim 72 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a method of utilizing a peptide "according to claim 6". Claim 6 is a peptide sequence wherein "a methionine residue at the N-terminus is optionally formylated". It is unclear what limitation this places on the claimed peptide.

36. Claims 24-26, 63, and 64 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims depend from rejected claims.

Conclusion

37. Claims 1, 2, 6, 7, 10-28, 58, 60, 62-73 are finally rejected.

38. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

39. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Wednesday from 9:00 AM to 7:30 PM EST. Thursday is the examiner's work at home day.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisors, Shannon Foley (571)272-0898, and Robert B. Mondesi (571)272-0956.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

August 18, 2008

Application Number**Application/Control No.**

10/534,082

**Applicant(s)/Patent under
Reexamination**

HINUMA ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645